

Please note that per the amendments to the specification above, all references of "2" to designate housing have been corrected, so that numeral "2" now designates only the holder. All of the drawings correctly depict the holder being designated by "2" and the housing being designated by "12". There is therefore no need to effect any changes in the drawings.

With regard to the designation of the space in the interior of holder 2, being submitted herewith are amended Figs. 4 and 5, the corrections effected thereon in red. Upon approval by the examiner, Figs. 4 and 5 will be corrected as shown in red. In addition, the specification has been amended to reflect that the space within the interior of holder 2 is designated "19".

With respect to the numerals "18", "34", "24" and "36", please note that the specification has been carefully amended to ensure that the respective spaces in the needle sheath and the interior of the holder are labeled 34 and 19, respectively. Aside from Figs. 4 and 5, there is no need for any other corrections in the remainder of the figures.

For the objection of numeral "20", needle 20 on page 9, line 14 of the specification has been amended to cannula.

In view of the above amendments, it is believed that all of the objections to the drawings have been corrected. Accordingly, the objections to the drawings are believed to be moot.

In view of the examiner's objection to claim 6, claim 6 has been amended to change the phrase "an other" to "another".

Claims 1-3, 5-8, 10-12, 14, 15, 17-20, 22, 23, 25 and 26 were rejected under 35 U.S.C. 102(b) as being anticipated by Hollister U.S. patent 5,277,311; and claims 9, 16

and 24 were rejected under 35 U.S.C. 103(a) as being obvious over Hollister in view of Imbert U.S. patent 6,027,482.

The instant invention relates to configuring a conventional Vacutainer holder such that a tortuous path may be provided to allow the sterilization of the needle cannula and at the same time prevent bacteria and/or other contaminants from infusing into the space covered by the needle sheath. To achieve this end, a sleeve 14 is added to the neck of the vacuum tube holder so as to create the structure, shown in Fig. 6, for effecting the tortuous path. Each of independent claims 1, 10 and 18 recites such a sleeve. In particular, claim 1 for example recites "a holder having one and other ends, said one end having an extension and a sleeve extending from said extension". Moreover, claim 1 recites "a sheath having an open end, said open end having a circumference that enables the sheath to matingly fit to said sleeve to establish an environment sealed against bacteria intrusion for said one end of said needle".

Hollister '311 does not disclose or suggest the sleeve structure set forth in the claims. In particular, Hollister '311 discloses a conventional vacuum tube holder or Vacutainer holder that includes a receptacle end 6 to which a double-ended needle assembly is threaded into. See column 3, lines 13-17. The receptacle end disclosed in Hollister '311 is shown as neck 8 in prior art Fig. 3 of the instant invention. Compare the prior art Fig. 3 with Fig. 4, which shows the sleeve extending from the neck 8, or receptacle end of the vacuum tube holder 2. With reference to Fig. 6, if sleeve 14 is not present, needle sheath 28 would merely hold against needle hub 24, so that no tortuous path is provided to allow sterilization of space 34 within needle sheath 28 and to prevent contaminants from entering space 34. Note that in each of the drawings shown in Hollister '311, the needle hub assembly 30, when threaded into receptacle end or neck 6, is flush with opening 8 so that there clearly is no sleeve that extends from the receptacle end 6 of any of the embodiments shown in the Hollister '311. Accordingly, the instant invention, per the above noted claims, is not anticipated by Hollister '311.

Nor does the combination of Hollister '311 and Imbert render as obvious the invention set forth in claims 9, 16 and 24. Granted Imbert does show a frangible label 86 serving as a tamper evidence seal. Yet such seal is used for the outer tab 58 and the luer collar 144 of a syringe. In contrast, the device disclosed in Hollister '311 comes in two separate pieces, namely the Vacutainer holder 2 and the double-ended needle assembly 30. Needle assembly 30 in turn is enclosed in its own container that comprises a first portion that covers needle 42 and another portion that acts as a needle sheath to cover needle 28. A tamper evidence seal is likely provided at the container. That being the case, there would be no need for any tamper evidence seal to be placed anywhere to Vacutainer holder 2, nor is there any need to. For when the double-ended needle assembly 38 is removed from its protective casing and threaded into receptacle end 6 for use, there no longer is any need for any tamper evidence seal, insofar as the double-ended needle assembly has already been exposed to the atmosphere and therefore is no longer sterile. Contrast this to the instant invention where everything stays sterile until use. And the tamper evidence seal that is affixed to the device of the instant invention as shown in Fig. 2 therefore truly provides for a tamper evidence seal, before the device is used. Thus, applicants respectfully submit that a person skilled in the art would not combine the teachings of Imbert and Hollister '311, since there is no need for any tamper evidence seal for the device of Hollister '311.

In view of the foregoing, applicants respectfully submit that the instant invention is patentable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and allow all of the pending claims at an early date.

Respectfully submitted,



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**VERSION TO SHOW MARKINGS TO SHOW CHANGES MADE**

**Attachment Specification Portions Pursuant to 37 C.F.R. 1.121(b)(1)(iii)**

Please amend the specification as follows:

Page 6, first full paragraph comprising lines 6-11:

To use, a double-ended needle assembly is threaded into neck 8 by way of its base so that one end of the double-ended needle would extend away from [housing] holder 2 while the other end of the double-ended needle extends within [housing] holder 2. Blood withdrawn from the patient is collected by a vacuum tube inserted to [housing] holder 2 at distal end 6. See also the prior art holder shown in Fig. 3.

Page 6, third full paragraph comprising lines 15-21:

As best shown in Fig. 4, [housing] holder 2 of the instant invention device has a sleeve 14 that extends, either integrally or otherwise, from neck 8. Moreover, enclosing the opening of the distal end 6 of [housing] holder 2 is a cover 16 that may be paper or other types of materials that would allow a sterilizing gas such as for example ethylene oxide (ETO) to pass into space [18] 19 of the housing, and yet at the same time prevents bacteria or other contaminants from intruding or passing into space [18] 19.

Page 6, last paragraph bridging to page 7:

With reference to Figs. 2 and 5, the device of the instant invention is shown to include a double-ended needle assembly 18 fitted to neck 8 of holder 2. Double-ended needle assembly 18 has a first cannula 20 that extends away from [housing] holder 2 and another cannula extending into space [18] 19 of [housing] holder 2, and which is shown to be covered by a rubber shroud 22. Needle assembly 18 has a base, or hub, 24 that includes a threaded portion 26 that is threaded to the internal threads 29 of neck 8. Once fully threaded into neck 8, base 24 is substantially positioned within sleeve 14. Although shown as being threadedly mated, in practice, for the instant invention, hub 24

of needle assembly 18 may be press fitted to neck 8. Hub 24 may be threaded to neck 8 of holder 2 with a torque force sufficient to ensure that once fitted, hub 24 could not be removed from neck 8.

Page 7, last paragraph bridging to page 8:

Another route via which sterilizing gas may be routed to space 34 is by way of space [18] 19 of holder 2. The path of the sterilizing gas from holder 2 is indicated by directional arrow 36. The threads 26t of the threaded portion 26 of hub 24 are configured such that, when mated with the internal threads 29 of neck 8, spaces such as 38 are effected between threaded portion 26 and neck 8. Thus, sterilizing gas could in fact be routed to space 34 by way of the opening at [housing] holder 2. As was noted earlier, cover 16 heat sealed to distal end 6 of holder 2 prevents bacteria from intruding into space [18] 19 of holder 2 while at the same time allows sterilizing gas to enter into space [18] 19 and, from there, eventually into space 34 defined by sheath 28. Cannula 20 may therefore be sterilized by the ETO gas input into space [24] 34 either by way of tortuous path 30 or by way of arrow 36. It should be noted, however, given that tortuous path 30 is closer to space [36] 34, most of the sterilization of space 34 in fact would be effected by way of tortuous path 30.

Page 9, first full paragraph comprising lines 3-17:

The device of the instant invention, as best shown in Figs. 2, 5 and 6, has fitted about its neck 8 a collar 10, which in turn has attached thereto, by means of a hinge 42, a housing 12 that is pivotable from the position as shown in Fig. 5 to a position substantially along the length of the longitudinal axis 44 of the device. A number of mechanisms in the form of hooks 46 may be integrally provided in housing 12. Alternatively, corresponding locking mechanisms such as for example anchors and clasping fingers may be provided at the lower portion of housing 12 and either sleeve 14 or collar 10 so that once housing 12 is pivoted to the position as indicated by longitudinal axis 14, those coacting mechanisms would coact to fixedly retain housing 12 in the longitudinal direction, thereby enveloping needle or cannula 20. Of course,

this is done after sheath 28 has been removed. The particulars of the coacting locking mechanisms at the housing 12 and collar 10 are disclosed in U.S. patent 5,469,622, the disclosure of which is incorporated by reference herein.

**Attachment Claims Pursuant to 37 C.F.R. 1.121(c)(1)(ii)**

Please amend claim 6 as follows:

6. (Amended) Apparatus of claim 1, wherein said housing comprises at least one locking portion that coacts with at least [an other] another locking portion at said collar or said sleeve to fixedly retain said housing along a longitudinal axis of said holder to cover said one end of said needle after said sheath has been removed from said sleeve.